

Remarks

I. Support for the Amendments

Support for the foregoing claim amendments may be found throughout the specification, and in the original claims. Specifically, support can be found, for example, at pages 13-22 of the specification as filed. The claims were amended due to the Examiner's requirement for election to a single sequence. The specification has been amended to remove the phrase "http:/" and to correct typographical errors. Support for the foregoing amendments to the specification can be found, for example, at pages 7 and 35 of the specification as filed. No new matter enters by way of these amendments.

II. Status of the Claims

By the foregoing amendments, claims 1-4 have been amended to reflect elected species. Upon entry of the foregoing amendments claims 1-7 are pending in the present application.

III. Rejection of claims 1-3 under 35 U.S.C. § 112, first paragraph

In the Office Action at pages 2 and 3, the Examiner has rejected claims 1-3 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an adequate written description. Applicants respectfully traverse this rejection.

The Examiner asserts that claims 1 and 2 lack an adequate written description due to the inadequacy of the definition of the phrase "algal proteins." The Examiner also asserts that

claim 3 lacks an adequate written description due to the lack of a definition for nucleic acid homologues. Applicants respectfully disagree with these assertions.

It is axiomatic that a specification need not teach, and preferably omits, information that is well-known to those of ordinary skill in the art. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986); *Lindemann Maschinenfabrik v. American Hoist and Derrick*, 730 F.2d 1452, 221 U.S.P.Q. 481 (Fed. Cir. 1984); *In re Wands*, 858 F.2d 731, 8 U.S.P.Q. 2d 1400 (Fed. Cir. 1988) The terms “homologue” and “algal protein” are well-known and in common usage in the art of plant molecular biology and biochemistry. As such, the rejection of claims 1-3 is improper.

Moreover, Applicants respectfully point out that the claims are to be read in light of the specification. *See In re Vogel*, 422 F.2d 438, 441, 164 U.S.P.Q. 619, 622 (C.C.P.A. 1970). The algal proteins are described throughout the specification, for example, at page 2, and in the references cited (and incorporated by reference) on page 33. Likewise, the specification teaches homologues and methods of sequence comparison that may be used to find related sequences at page 90 and page 7-12, respectively. Accordingly, Applicants assert that the rejection of the present claims under 35 U.S.C. §112, first paragraph, as lacking written description is improper and should be withdrawn.

In order to facilitate prosecution, however, Applicants have amended claims 1 and 2, and submit that the indefiniteness rejection should be withdrawn as inapplicable to the presently amended claims.

IV. The Objection to the Specification

In the Office Action at page 3, the Examiner has objected to the specification because it allegedly contains embedded hyperlinks and/or other forms of browser executable code.

Applicants have accommodated this objection by amendment of the specification to remove all “http://” prefixes and underlining. No new matter was added by way of this amendment.

A URL is not considered to be browser executable code if it is not either preceded with *http://* or placed between the symbols “< >.” M.P.E.P. § 608.01, page 600-60, Examiner Note. As such, the URLs present in the application, as amended, are not browser executable code, and would not be interpreted by a browser as a link to another web site when the document is placed on the USPTO web site. Reconsideration and withdrawal of this objection are respectfully requested.

V. Rejection of Claims Under 35 U.S.C. § 101

In the Office Action at pages 3-6, the Examiner has rejected claims 1-7 under 35 U.S.C. § 101, for allegedly lacking a patentable utility. Applicants respectfully traverse this rejection.

The Examiner acknowledges that the specification describes multiple utilities for the present invention, including “markers, the isolation of polypeptides, hybridization probes, primers, the isolation of full-length cDNAs or genes, which would be used to make protein and optionally further usage for mapping and numerous other generic genetic engineering usages, as well as genetic therapy, such as antisense usage.” Office Action at page 4.

However, the Examiner contends that none of these utilities constitute a “substantial” or “specific” utility. Applicants respectfully disagree with this assertion.

It is well established that “when a properly claimed invention meets at least one stated objective, utility under section 101 is clearly shown.” *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 958, 220 U.S.P.Q. 592, 298 (Fed. Cir. 1983). The present specification describes many objectives that are met by the present invention. In addition to the utilities described by the Examiner (quoted above), the claimed nucleic acid molecules are useful for obtaining protein molecules, determining the presence and/or identity of polymorphisms, measuring the levels of an mRNA in a sample, determining the location of a corresponding DNA sequence on a physical or genetic map, probing for other molecules, generating primers, obtaining other nucleic acid molecules from the same species, obtaining related protein coding sequences, obtaining promoters and other flanking genetic elements, screening cDNA genomic libraries, obtaining nucleic acid homologs, detecting and characterizing gene expression, etc. *See* specification at pages 90-108, under the heading “Uses of the Agents of the Present Invention.”

Many of these uses are directly analogous to a microscope. An important utility of a microscope resides in its use to identify and characterize the structure of biological tissues in a sample, cell or organism. Significantly, the utility of the microscope under 35 U.S.C. § 101 is not compromised by its use as a tool in this manner. Many of the presently disclosed utilities are directly analogous to the utilities of a microscope, *i.e.*, the claimed nucleic acid molecules may be used to identify and characterize other nucleic acid molecules within a sample, cell or organism. Such utility is indistinguishable from the legally sufficient utility

of a microscope. Thus, the presently disclosed sequences possess the requisite utility under 35 U.S.C. § 101.

In the Office Action, the Examiner provides no evidence challenging the disclosed utilities for the presently claimed nucleic acid molecules. Rather the Examiner attempts to undermine the existing utilities by stating, “[t]he claimed nucleic acid compounds are not supported by a specific asserted utility because the disclosed uses of these compositions are not specific and are generally applicable to any nucleic acid.” Office Action at page 4. In short, the Examiner suggests that the asserted utilities are legally insufficient simply because other molecules can be used for the same purpose. This position is wrong as a matter of law – there is no requirement of exclusive utility in the patent law. *See Carl Zeiss Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180, 20 U.S.P.Q.2d 1094, 1100 (Fed. Cir. 1991) (“An invention need not be the best or the only way to accomplish a certain result...”).

Moreover, this position offends the sensibilities. For example, such an argument implies that a new golf club has no legal utility because other golf clubs can be used for the same purpose, *i.e.*, hitting golf balls. Such a result is not only untenable, but requires reading “into the patent laws limitations and conditions which the legislature has not expressed,” a practice condemned by the Supreme Court. *See Diamond v. Chakrabarty*, 447 U.S. 303, 308, 306 U.S.P.Q. 193, 196 (1980), *quoting United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 199, 17 U.S.P.Q. 154, 163 (1933). Thus, it must be the case that a utility, generic to a broad class of molecules, does not compromise the specific utility of an individual member of that class.

As noted above, the claimed nucleic acid molecules have many utilities. Some of these utilities may be common to a broader class of molecules. For instance, nucleic acid sequences may generally be used to identify and locate related sequences. However, when used in this manner, the result is not generic. Rather, the claimed nucleic acid molecules will identify a *unique* subset of related sequences. This subset of related sequences is specific to the claimed sequences and cannot be identified by any generic nucleic acid molecule. For example, a random nucleic acid molecule would not provide this specific utility. Referring again to the golf club analogy, the club is still generically hitting a golf ball, but is uniquely designed to hit a ball in a manner that is distinct from other clubs. Once again, Applicants assert that the claimed nucleic acid sequences exhibit the requisite utility under 35 U.S.C. § 101.

Surprisingly, the Examiner notes that the credibility of the presently asserted utilities has not been assessed. Office Action at pages 5-6. Credibility is precisely the issue that the courts have emphasized in evaluating the adequacy of an asserted utility. Utility is determined “by reference to, and a factual analysis of, the disclosure of the application.” *In re Ziegler*, 992 F.2d 1197, 1201, 26 U.S.P.Q.2d 1600, 1603 (Fed. Cir. 1993), *quoting Cross v. Iizuka*, 752 F.2d 1040, 1044, 224 U.S.P.Q. 739, 742 (Fed. Cir. 1985). The Examiner “has the initial burden of challenging a presumptively correct assertion of utility in the disclosure.” *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). The utilities asserted in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *Id.* The Examiner “must do more than merely question – [she] must set forth factual reasons which would lead one skilled in

the art to question the objective truth of the statement of operability.” *In re Gaubert*, 524 F.2d 1222, 1225-26, 187 U.S.P.Q. 664, 666 (C.C.P.A. 1975) (emphasis in original); MPEP § 706.03(a)(1) (“Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility, unless countervailing evidence can be provided...”).

Here the Examiner has not even attempted to meet this burden. Thus, the Examiner’s admission that the credibility of the disclosed utilities is not challenged is tantamount to an admission that no proper rejection has been made.

In view of the above, Applicants contend that the claimed nucleic acid molecules are supported by credible, specific and substantial utilities disclosed in the specification. Moreover, the Examiner has failed to raise any credible evidence challenging the presently asserted utilities. Consequently, the rejection of claims 1-7 is improper. Reconsideration and withdrawal of this rejection are respectfully requested.

VI. Rejection of Claims Under 35 U.S.C. § 112, First Paragraph

In the Office Action, at page 6, the Examiner has rejected claims 1-7 as not being enabled by the specification because the claimed invention allegedly lacks utility. Applicants respectfully traverse this rejection. This rejection has been overcome by the foregoing arguments regarding utility. Thus this rejection under 35 U.S.C. § 112, first paragraph is improper. Reconsideration and withdrawal are respectfully requested.

VII. Summary

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

In the Specification at page 7, lines 13-22:

Similarity analysis includes database search and alignment. Examples of public databases include the DNA Database of Japan (DDBJ)(<http://www.ddbj.nig.ac.jp/>); [Genebank] Genbank (<http://www.ncbi.nlm.nih.gov/web/Genbank/Index.html> html); and the European Molecular Biology Laboratory Nucleic Acid Sequence Database (EMBL) (http://www.ebi.ac.uk/ebi_docs/embl_db.html). A number of different search algorithms have been developed, one example of which are the suite of programs referred to as BLAST programs. There are five implementations of BLAST, three designed for nucleotide sequences queries (BLASTN, BLASTX, and TBLASTX) and two designed for protein sequence queries (BLASTP and TBLASTN) (Coulson, *Trends in Biotechnology*, 12:76-80 (1994); Birren, *et al.*, *Genome Analysis*, 1:543-559 (1997), all of which are incorporated by reference in their entirety).

In the Specification at page 35, lines 10-18:

Exogenous genetic material may be transferred into a plant cell by the use of a DNA vector or construct designed for such a purpose. Vectors have been engineered for transformation of large DNA inserts into plant genomes. Binary bacterial artificial chromosomes have been designed to replicate in both *E. coli* and *A. tumefaciens* and have all of the features required for transferring large inserts of DNA into plant chromosomes (Choi and Wing, <http://genome.clemson.edu/protocols2-nj.html> July, 1998). A_pBACwich system has been developed to achieve site-directed integration of DNA into

the genome. A 150 kb cotton BAC DNA is reported to have been transferred into a specific *lox* site in tobacco by biolistic bombardment and *Cre-lox* site specific recombination.

In the claims

1. (Once amended) A substantially purified nucleic acid molecule that [encodes an algal protein or fragment thereof comprising] comprises a nucleic acid sequence [selected from the group consisting] of SEQ ID NO: 1 [through SEQ ID NO: 5674].
2. (Once amended) The substantially purified nucleic acid molecule according to claim 1, wherein [said algal protein or fragment thereof is] said nucleic acid molecule encodes a *Cyanidium caldarium* protein or fragment thereof.
3. (Once amended) A substantially purified homologue of a *Cyanidium caldarium* protein [homologue] or fragment thereof encoded by a nucleic acid molecule that comprises a nucleic acid sequence [selected from the group consisting] of SEQ ID NO: 1 [through SEQ ID NO: 5674].
4. (Once amended) A transformed cell having a nucleic acid molecule which comprises:
 - (A) an exogenous promoter region which functions in said cell to cause the production of a mRNA molecule; which is linked to
 - (B) a structural nucleic acid molecule, wherein said structural nucleic acid molecule comprises a nucleic acid sequence [selected from the group consisting] of SEQ ID NO: 1 [through SEQ ID NO: 5674]; which is linked to

(C) a 3' non-translated sequence that functions in said cell to cause termination of transcription and addition of polyadenylated ribonucleotides to a 3' end of said mRNA molecule.